

JUL 24 2002

Premarket Notification – 510(k)**ADVIA Centaur 125 II Immunoassay****510(k) Summary of Safety and Effectiveness**

This summary of safety and effectiveness is being submitted in accordance with the requirements of The Safe Medical Devices Act of 1990 (SMDA 1990) and 21 CFR 807.92.

The assigned 510(k) number is:

7.1 General Information

Date of Summary Update:

Applicant: Kenneth T. Edds, Ph.D.
Manager, Regulatory Affairs
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
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Ken.edds.b@bayer.com

Owner: Bayer Corporation
Business Group Diagnostics
511 Benedict Ave.
Tarrytown, NY 10591
Establishment Registration No: 2432235

Manufacturer: Bayer Corporation
333 Coney Street
Walpole, MA 02032
Establishment Registration No: 1219913

Device Name: ADVIA Centaur® CA 125 II assay

Common or Usual Name: Chemiluminescence immunoassay kit for the determination of CA 125 antigen using Bayer Corporation's ADVIA Centaur automated analyzer.

Classification:
Name: Bayer ADVIA Centaur CA 125 II Assay
Class: II
CFR: 21 CFR 866.6010
Product Code: 82 LTK

This submission was prepared in accordance with "Guidance Document for Submission of Tumor Associated Antigen Premarket Notifications".

Substantial Equivalence To: Bayer Immuno-1 CA 125 II

510(k) Number: K983715

7.2 Intended Use

For *in vitro* diagnostic use in the quantitative, serial determination of CA 125 in human serum and to aid in the management of patients with ovarian carcinoma using the ADVIA Centaur® System. The test is intended for use as an aid in monitoring patients previously treated for ovarian cancer. Serial testing for CA 125 in the serum of patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of cancer recurrence. The test is also intended for use as an aid in the management of ovarian cancer patients with metastatic disease by monitoring the progression or regression of disease in response to treatment. It is recommended that the Bayer ADVIA Centaur CA 125 II assay be used under the order of a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.

7.3 Device Description

The ADVIA Centaur CA 125 II assay is a fully automated, single step sandwich immunoassay using direct, chemiluminescent technology. The Lite Reagent is composed of the monoclonal mouse antibody, OC125, specific for CA 125, labeled with acridinium ester and the monoclonal mouse antibody M11, specific for CA 125, labeled with fluorescein. The Solid Phase is composed of purified monoclonal mouse capture antibody, which is covalently coupled to paramagnetic particles. The sample is incubated with both Lite Reagent and Solid Phase simultaneously for 40 minutes. After incubation, the immuno-complex is washed. The measured chemiluminescence is directly proportional to the quantity of CA 15-3 antigen in the sample.

7.4 Comparison to the Predicate Device

The ADVIA Centaur CA 125 II immunoassay kit is similar to the Immuno-1 CA 125 II kit in the indications for use, format, performance characteristics, and results. The ADVIA Centaur tests differ mainly in their signal system as compared to the Immuno-1 principle. In the ADVIA Centaur method, a chemiluminogenic molecule (acridinium ester) is used to replace the Alkaline Phosphatase signal used in the Immuno-1 assay.

7.5 Equivalence to Predicate Device

For 227 samples in the range of 2.3 to 466.6 U/mL, the relationship of the ADVIA Centaur CA 125 II assay to the Immuno 1™ CA 125 II assay is described by the following equation (calculated using Deming Regression):

$$\text{ADvia Centaur CA 125 II} = 1.025 \text{ (Immuno 1)} + 1.14 \text{ U/mL}$$

The correlation coefficient r is 0.992

The data demonstrate substantial equivalence of the ADVIA Centaur CA 125 II assay to the FDA-cleared Bayer Immuno-1 CA 125 II assay as an adjunctive test for use in the management (monitoring) of metastatic ovarian cancer patients during the course of disease and therapy and for the detection of disease recurrence.

7.6 Monitoring Cancer Patients for Progression or Response

A retrospective clinical study was conducted to evaluate Centaur CA 125 II values in 44 ovarian cancer patients during the course of disease and therapy. Changes in the clinical status of patients were compared to changes in Centaur CA 125 II results. The sensitivity of longitudinal measurements using the method was 93.5% and the specificity was 38.5%.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Kenneth T. Edds, Ph.D.
Regulatory Affairs
Bayer Corporation
Business Group Diagnostics
511 Benedict Avenue
Tarrytown, NY 10591-5097

JUL 24 2002

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Re: K020828

Trade Name: Bayer Advia Centaur CA 125 assay

Regulation Number: 21 CFR 866.6010

Regulation Name: Tumor-associated antigen immunological test system

Regulatory Class: II

Product Code: LTK

Dated: March 12, 2002

Received: March 14, 2002

Dear Dr. Edds:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indication for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020828

Device Name: Bayer Diagnostics ADVIA Centaur CA 125 Assay

Indications for Use:

For *in vitro* diagnostic use in the quantitative, serial determination of CA 125 in human serum and to aid in the management of patients with ovarian carcinoma using the ADVIA Centaur® System. The test is intended for use as an aid in monitoring patients previously treated for ovarian cancer. Serial testing for CA 125 in the serum of patients who are clinically free of disease should be used in conjunction with other clinical methods used for the early detection of cancer recurrence. The test is also intended for use as an aid in the management of ovarian cancer patients with metastatic disease by monitoring the progression or regression of disease in response to treatment. It is recommended that the Bayer ADVIA Centaur CA 125 II assay be used under the order of a physician trained and experienced in the management of gynecological cancers. This assay is not intended for screening or diagnosis of ovarian cancer or for use on any other system.

J. Reeves for S. Altair
(Division Sign-Off)
Division of Clinical Laboratory Services

510(k) Number K020828

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE, IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)